

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in the reply filed on July 5, 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 1 is objected to because of the following informalities: the accepted spelling of an -SH group is "sulfhydryl", not "sulhydril" as recited in line 2 of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 - 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Squiller et al. (US 5,559,204).

Squiller et al. disclose a polymer prepared by reacting polyamines, a prepolymer comprising at least one amine, with aldehydes and an optionally substituted maleic or fumaric acid esters (col 7, ln 4 - 6). The formula of the dicarboxylic acid esters is shown at col 8, ln 3 with exemplary dicarbonic acid esters including the disubstituted dimethyl, diethyl and di-n-butyl esters and also the corresponding acid esters containing methyl in the 2- and/or 3- position (col 8, ln 1 - 8).

In regards to claim 2, the dicarbonic acid groups will react with the terminal groups of the prepolymer to endcap the prepolymer with the unsaturated mono-esterified dicarbonic acid. As the present claims are drawn to a product and not a process of preparation, the limitations of claim 4 are met regardless of how the esterified form is prepared as the same chemical compound results. The methyl, ethyl and n-butyl esters can be formed by esterification with a C₁, C₂ or C₄ alkyl alcohol.

5. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammer et al. (US 3,972,961).

Hammer et al. discloses the reaction of the amine containing oligomer caprolactam/hexylamine polymer (CL/HA) with monoethyl ester of maleic acid (example 70, col 41). In regards to claim 2, the dicarbonic acid groups will react with the terminal groups of the prepolymer to endcap the prepolymer with the unsaturated mono-esterified dicarbonic acid. As the present claims are drawn to a product and not a

Art Unit: 1618

process of preparation, the limitations of claim 4 are met regardless of how the esterified form is prepared as the same chemical compound results. The ethyl ester can be formed by esterification with a C₂ alkyl alcohol.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1618

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 - 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squiller et al. (US 5,559,204).

Squiller et al. disclose a polymer prepared by reacting polyamines, a prepolymer comprising at least one amine, with aldehydes and an optionally substituted maleic or fumaric acid esters (col 7, ln 4 - 6). The formula of the dicarboxylic acid esters is shown at col 8, ln 3 with exemplary dicarbonic acid esters including the disubstituted dimethyl, diethyl and di-n-butyl esters and also the corresponding acid esters containing methyl in the 2- and/or 3- position (col 8, ln 1 - 8).

Squiller et al. does not exemplify fumaric acid monoethyl ester as an optionally substituted maleic or fumaric acid ester that can be used to prepare the polymer.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a mono-esterified fumaric acid with a single ethyl group. Squiller et al. discloses disubstituted fumaric acid with ethyl groups and monosubstituted version with methyl groups as examples of optionally substituted fumaric acid compounds that can be used to prepare a macromer as required by the instant claims. Homologs, such as the monomethyl fumarate exemplified by Squiller et al. and monoethyl fumarate that differ by a single $-CH_2-$ groups, are generally of sufficient structural similarity that they would be expected to have the same properties (see MPEP 2144.09 II).

In regards to claim 2, the dicarbonic acid groups will react with the terminal groups of the prepolymer to endcap the prepolymer with the unsaturated mono-esterified dicarbonic acid. As the present claims are drawn to a product and not a process of preparation, the limitations of claim 4 are met regardless of how the esterified form is prepared as the same chemical compound results. The methyl, ethyl and n-butyl esters can be formed by esterification with a C₁, C₂ or C₄ alkyl alcohol.

10. Claims 1 - 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney et al. (US 6,083,524) in view of Hammer et al. (US 3,972,961).

Sawhney et al. discloses water-soluble, biocompatible, biodegradable macromers including at least one biodegradable block with a carbonate or dioxanone group with a biodegradable linker and at least one polymerizable group (col 3, ln 5 - 14). Poly(ethylene glycol) is a preferred water-soluble block but poly(vinyl alcohols), poloxamines, various polysaccharides containing hydroxyl groups and proteins, with amines and possible sulfhydryl groups, may also be used as the water soluble region (col 5, ln 39 - 53). Multiple water soluble groups can be joined by linkers such as unsaturated dicarboxylic acids such as maleic or fumaric acid, esterified with degradable groups and conjugated at one or both ends with hydrophilic groups such as PEG (col 5, ln 67 - col 6, ln 8). Unsaturated dicarboxylic acid including fumaric acid can be used as the polymerizable groups or derivatives of the groups also used (col 7, ln 12- 36). Among the preferred polymers for the biodegradable block are poly(glycolic

Art Unit: 1618

acid), poly(DL-lactic acid), poly(L-lactic acid) and poly(epsilon-caprolactone) (col 6, In 14 - 29).

Sawhney et al. does not explicitly identify mono-esterified ester of a dicarboxylic acid ester such as fumaric acid as the polymerizable group reaction.

Hammer et al. discloses that various compounds can be added to a polymer to provide amine reactive sites, including compounds of formula (b) that includes maleic and fumaric acid and monoesters of these compounds (col 4, In 6 - 50). Monoethyl fumarate and lower monoalkyl esters of fumarate can be used to prepare various trunk copolymers (col 6, In 55 - col 7, In 3). The graft copolymers can include polycaprolactams, polymers of organic oxides such as ethylene oxide and polymers of lactones (col 7, In 4 - 34). For example, in example 70, the polyamide polycaprolactam is reacted with ethylene/monoethyl ester of maleic acid (col 41, In 1 - 15).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate monoesters of dicarboxylic acids such as the ethyl monoesters of fumaric or maleic acid with the biodegradable polymers taught by Sawhney et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Sawhney et al. discloses dicarboxylic acids and their derivatives as biodegradable linkers for the preparation of macromers and Hammer et al. discloses that monoethyl esters can be attached to polymers such as polycaprolactams, polylactones and polyethylene oxide (polyethylene glycol).

In regards to claim 2, the dicarbonic acid groups will react with the terminal groups of the prepolymer to endcap the prepolymer with the unsaturated mono-esterified dicarbonic acid. As the present claims are drawn to a product and not a process of preparation, the limitations of claim 4 are met regardless of how the esterified form is prepared as the same chemical compound results. The methyl and ethyl esters can be formed by esterification with a C₁ or C₂ alkyl alcohol.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NISSA WESTERBERG whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Primary Examiner, Art Unit 1618